

I. AMENDMENTS TO THE CLAIMS

This listing of the claims will replace all prior versions and listings of claims in the application.

1. (currently amended) A device for hygienic ultrasonic interrogation of a skin interrogation site, comprising:

a) a shaped holder for an ultrasonic probe adapted for hygienic skin-interrogation of tissues subjacent to a skin interrogation site, said holder ~~[[is]]~~ adapted to fit at least an interrogation surface of said ultrasonic probe, ~~and said holder includes~~ including 1) a securing portion for securing said holder to said ultrasonic probe and 2) an interrogation window in acoustic alignment with at least a section of said interrogation surface, and

b) a sonolucent film covering said interrogation window, wherein the distance between the interrogation surface of the probe and the interrogation window is less than approximately 1 cm, the holder positioned and sized to prevent direct contact between the interrogation surface of the probe and the skin, but without introducing a substantial standoff distance between the interrogation surface of the probe and the interrogation window.

2. (previously presented) The device of claim 1, wherein said holder is made of a holder-polymeric material and said sonolucent film is made of a sonolucent-polymeric material.

3. (previously presented) The device of claim 2, wherein said sonolucent-polymeric material is more flexible than said holder-polymeric material.

4. (currently amended) The device of claim 3, wherein said sonolucent film is ~~heated~~ heat welded or sealed to said holder.

5. (previously presented) The device of claim 3, wherein said holder-polymeric material is a rigid, injection molded polymer.

6. (previously presented) The device of claim 1, wherein said interrogation window is made of a rigid polymer with a substantially planar surface that holds said sonolucent film.

7. (previously presented) The device of claim 6, wherein said sonolucent film is a substantially planar interrogation surface.

8. (previously presented) The device of claim 6, wherein said sonolucent film has a substantially planar interrogation surface after an ultrasonic probe is inserted into said holder.

9. (previously presented) The device of claim 1, wherein said sonolucent film is an acoustic coupling material made of a pliable polymer matrix.

10. (previously presented) The device of claim 9, wherein said sonolucent film includes an applied gel on said sonolucent film's exterior interrogation-side to enhance acoustic communication.

11. (previously presented) The device of claim 9, wherein said sonolucent film includes an applied gel on said sonolucent film's interior interrogation-side to enhance acoustic communication.

12. (previously presented) The device of claim 1, wherein said interrogation window is a molded portion of said holder.

13. (previously presented) The device of claim 12, wherein said interrogation window is of about the same surface area as said interrogation surface of said ultrasonic probe for which said holder is designed.

14. (previously presented) The device of claim 13, wherein said holder further comprises securing members for securing said holder to said ultrasonic probe.

15. (previously presented) The device of claim 12, wherein said holder and said sonolucent film are comprised of one acoustic coupling material and said holder has a region with a cross sectional thickness greater than said sonolucent film's cross sectional thickness.

16. (previously presented) The device of claim 13, further comprising an ultrasound probe adapted to fit said holder.

17. (previously presented) The device of claim 15, wherein said interrogation window is about 10 cm² or less in surface area.

18. (previously presented) The device of claim 1, wherein said holder is made of a molded plastic and is contained in a hygienic container to protect it from contamination prior to use.

19. (currently amended) A device for ultrasonic interrogation from a skin interrogation site, comprising:

a plurality of shaped holders for an ultrasonic probe adapted for skin-interrogation of tissues subjacent to a skin interrogation site, said ~~holder is~~ holders adapted to fit at least an interrogation surface of said ultrasonic probe, ~~and said holder includes 1)~~ including a securing portion for securing said holder to said ultrasonic probe and ~~2)~~ an interrogation window in acoustic alignment with at least a section of said interrogation surface, and a sonolucent film covering said interrogation window, the probe's interrogation surface and the interrogation window being separated by less than approximately 1 cm such as to prevent direct contact between the interrogation surface of the probe and the skin interrogation site, but without introducing a substantial standoff distance between the interrogation surface and the interrogation window, and wherein each shaped holder has an exterior contour and an interior contour and said exterior contour is configured to fit into an interior contour of another holder.

20-29 (canceled)

30. (currently amended) A hygienic removable shaped holder for an ultrasound probe, said removable shaped holder comprising a proximal region for interrogation of an exterior interrogation surface, said proximal region is adapted for acoustic alignment with an ultrasound source or detector, said proximal region includes an interrogation surface that permits interrogation with an ultrasound probe and a distal region slidably engagable with said ultrasound probe while maintaining said acoustic alignment, wherein the distance between the ~~interrogation surface of the probe and the interrogation window~~ is less than approximately 1 cm so the probe is close to but not directly touching the interrogation surface during an ultrasound interrogation, the holder therefore preventing direct contact between the probe and the exterior

interrogation surface, but without introducing a substantial standoff between the probe and the interrogation window.

31. (previously presented) The device of claim 30, wherein said proximal region is molded.

32. (previously presented) The device of claim 30, wherein said interrogation surface is a film that passes ultrasonic waves.

33. (previously presented) The device of claim 32, wherein said film is more rigid than a polyurethane film of about 2 mil, and made of a polymer that passes at least 90 percent of ultrasonic waves reaching said film's surface.

34. (previously presented) The device of claim 30, wherein a portion of said film maintains a substantially planar surface without insertion of an ultrasound probe into said removable holder.

35. (previously presented) The device of claim 30, wherein said distal region is molded.

60. (currently amended) An injection molded device for hygienic ultrasonic interrogation of an exterior interrogation surface, comprising a rigid, plastic holder for an ultrasound source or detector, said rigid, plastic holder ~~is of~~ having a generally predetermined shape and three dimensional dimensions without an inserted ultrasound source or detector, said rigid, plastic holder comprising an interrogation region for interrogation of ~~an~~ the exterior interrogation surface, said interrogation region is dimensioned to snugly fit over a housing for

said ultrasound source or detector while permitting interrogation through said interrogation region and said interrogation region ~~engages~~engaging with said housing, wherein the holder includes a predetermined quantity of acoustic gel material, allowing acoustic coupling between the ultrasonic source or detector and the exterior interrogation surface, but preventing direct contact between the ultrasound source or detector and the exterior interrogation surface, and without introducing a substantial standoff distance between the ultrasonic source or detector and the interrogation region, said standoff distance, if any, being less than approximately 1 cm.

61. (previously presented) The injection molded device of claim 60, wherein the predetermined quantity of acoustic gel material comprises a machine applied acoustic gel layer on said interrogation region to facilitate acoustic coupling between said interrogation region and said ultrasound source or detector.

62. (previously presented) The injection molded device of claim 60, further comprising a cap that snugly fits over said interrogation region intended to be in contact with said exterior interrogation surface.

70. (currently amended) An ultrasound system for hygienic ultrasonic interrogation of an exterior interrogation surface, comprising:

a) a rigid, plastic holder for an ultrasound source or detector, said rigid, plastic holder ~~is of~~ having a generally predetermined shape and three dimensional dimensions without an inserted ultrasound source or detector, said rigid, plastic holder comprises an interrogation region for interrogation of ~~an~~the exterior interrogation surface, said interrogation region is dimensioned to snugly fit over a housing or frame for said ultrasound source or detector while

permitting interrogation through said interrogation region and said interrogation region ~~engages~~
engaging with said ultrasound source or detector housing or frame, allowing acoustic coupling
between the ultrasonic source or detector and the exterior interrogation surface, but preventing
direct contact between the ultrasonic source or detector and the exterior interrogation surface,
and without introducing a substantial standoff distance between the ultrasonic source or detector
and the interrogation region, said standoff distance, if any, being less than approximately 1 cm,

- b) an ultrasound probe mechanically compatible with said rigid, plastic holder,
~~wherein~~ the holder configured to be mechanically compatible with a plurality of differently sized
ultrasonic probes, and
- e) an ultrasound device for ultrasound interrogation, signal processing and
conveyance of interrogation information.

71-78 (canceled)

82. (previously presented) The device of claim 1, wherein , the securing portion of
the holder configured to secure a plurality of differently sized ultrasonic probes.

83. (previously presented) The hygienic removable holder of claim 30 further
including a collar which secures the probe within the holder, said collar being configured to
received more that one size probe.

84. (new) The device of claim 19, wherein the exterior contour and the interior
contours are substantially similar.

85. (new) The device of claim 1, further comprising a compressible member disposed on a distal portion of the securing portion for securing the holder to a plurality of differently sized probes.

86. (new) The device of claim 19, further comprising a compressible member disposed on a distal portion of the securing portion for securing the holder to a plurality of differently sized probes.

87. (new) The device of claim 60, further comprising a distal interior portion of the holder having a compressible member disposed thereon for securing the holder to a plurality of differently sized probes.